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I, KAY WARD, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. PQ 0904 for a patent by WILLIAM S PETERS filed on 10 June 1999.

WITNESS my hand this
Twenty-ninth day of June 2000

K Ward

KAY WARD
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SUPPORT AND SALES

AUSTRALIA

Patents Act 1990

WILLIAM S PETERS

PROVISIONAL SPECIFICATION

Invention Title:

Heart Assist Device and System

The invention is described in the following statement:

The present invention relates to heart assist devices, systems and methods.

Currently the only real options for improvement of end-stage heart failure are medical therapy, left ventricular assist devices (LVADs) and transplantation. ACE (Angiotensin Converting Enzyme) inhibitors unload the heart and prolong survival [1]. LVADs pump blood and significantly improve life style and survival, but are complicated to implant, maintain and remove, with relatively high complications relating to bleeding, infection, thromboembolism, and device malfunction [2].

The transplant rate has stabilised at 2,000 per year in the USA, being limited by organ availability. Transplantation achieves a 75% five year survival rate and a 65% ten year survival rate with significant improvements in functional class [3].

The number of people awaiting heart transplantation steadily increases and they are a sicker group, with increasing numbers requiring hospitalisation, ionotropes, short-term percutaneous trans-femoral intra-aortic balloon pumping and/or LVAD.

The Institute of Medicine has estimated that by the year 2010, up to 70,000 patients will be candidates for permanent mechanical circulatory support systems [4].

Over the last ten years, LVADs have been well proven to save lives, acting as bridges to transplantation for critically ill patients. Recently, LVADs have been considered as alternatives to transplantation, and very recently, have been explanted in a few patients who have shown recovery. This latest realisation is starting to gather a lot of interest as workers focus on recovery of the failing heart. LVADs totally unload the left ventricle and many believe that the heart will then recover. Moreover there is evidence beyond the few patients in whom devices have been removed that there is reversal in markers of heart failure [5-7]. On the other hand, others have described an increase in myocardial fibrosis [8] which raises a question of whether the heart is being unloaded too much.

The intra-aortic balloon pump (IABP) was first proposed in the 1960s as a method of partial support for the acutely failing heart, for example, after heart surgery or heart attack. It was built as a long thin catheter [10-14 Fr] with an elongated balloon at its tip [volume 30-40 ml]. The balloon was inserted via the femoral artery and inflated and deflated in time with the

heart beat. Inflation in diastole causes a diastolic pressure augmentation and increases coronary artery blood flow and deflating in systole (triggered by the R wave of the ECG) reduces the afterload, or the pressure head against which the left ventricle has to eject blood. Early investigators determined that the best and most efficient balloon position was closest to the heart, i.e., in the ascending aorta. However, in recent times, the balloon is positioned via the femoral artery in the descending aorta for short term (1-10 days) use. There is substantial proof beyond doubt that counterpulsation works very well in the short-term to assist hearts to recover when drugs (ionotropes etc.) are insufficient or inappropriate to support the cardiovascular system.

Very early work demonstrated chronic or long term heart failure improved with prolonged bed rest, that is, the heart is working at a reduced load and slowly recovers to a degree. This advantage is offset by a general loss of physical condition or prolonged bed rest.

Intra-aortic balloon heart pumps operating in counterpulsation assist the heart function. When inflated, the balloon propels blood distally in within the aorta to improve blood circulation in the patient. Moreover blood is forced into the coronary arteries to help nourish and strengthen the heart muscle. However, the balloon comes into direct contact with the blood flowing into the aorta, which can cause damage to the blood cells and there is a risk of thromboembolism. In addition, current intra-aortic balloon pump systems are inflated by means of a tube passing through the body, the tube connecting the balloon to an external compressor. The opening for the tube to enter the body provides a possible site of infection or other injury. Additionally, the use of a gas to inflate the balloon is not an entirely safe operation since any leakage of gas from the balloon into the blood stream could cause an air embolus.

Aortic compression (periaortic diastolic compression) has been described as a means to increase coronary blood flow. For example, US Patent No. 4,583,523 describes an implantable heart assist device including an elongated assembly extending transversely between the ribs of a patient from the rib cage to the aorta of the heart to be assisted. The assembly includes an aorta compressing device at the front end and a mounting device at the rear end thereof to support the device from the ribs of the patient. A motive device actuates and deactivates the compressing device alternatively to help pump blood through the aorta in a counterpulsation mode of

operation. Although this device has advantages for many applications, it does require relatively complicated surgery to implant/explant the device, particularly in regard to the need to mount the device, including its motive means, to the ribs of the patient. Moreover the mounting arrangement and motive means of the device have to be positioned outside the rib cage, making the presence of the device more noticeable to the patient. There is also substantial risk of infection with the device coming through the skin. Furthermore, because the device is attached/mounted to the ribs, there may be shear stresses on the aorta as the rib cage moves with inspiration/expiration. These stresses may cause untoward damage of the aorta.

US Patent No. 4,979,936 describes an autologous biologic pump in the form of an apparatus using skeletal muscle formed into a pouch which then surrounds a collapsible, shape-retaining bladder. The bladder is connected to a second bladder enclosed in a sheath around a portion of the aorta. The bladders are filled with a fluid such that when the skeletal muscle contracts in response to an electrical stimulation, the fluid is forced from the first bladder into the bladder sheathed around with the aorta, expanding that bladder and forcing the aorta to compress. Although this approach may be useful in some circumstances, it is doubtful that it is suitable for long term in that the muscle function would probably degrade over time. Furthermore, the muscle has to be "trained" for many weeks before the device can be relied on to assist blood circulation.

It would be desirable to have a heart assist device that could be quickly and totally implanted in a relatively easy manner and with minimum trauma to the patient. Moreover, it would be desirable for such a device to allow ambulation with low risk of complications.

In a first aspect, the present invention provides an implantable device for assisting the functioning of the heart of a subject, including:

means for externally engaging and compressing the aorta;

motive means for cyclically actuating and de-activating the compressing means to help blood pump through the aorta;

wherein the compressing means and the motive means are fully implantable within the thoracic cavity of the subject and wherein the compressing means and/or motive means include means adapted for

attachment to the aorta and/or surrounding tissue within the thoracic cavity of the subject.

In a further aspect, the present invention provides an implantable system for assisting the functioning of the heart of a subject, the system including:

an implantable device for assisting the functioning of the heart of a subject, including:

means for externally engaging and compressing the aorta;

motive means responsive to control signal(s) for actuating and de-activating the compressing means cyclically to help blood pump through the aorta, wherein the compressing means and the motive means are fully implantable within the thoracic cavity of the subject and wherein the compressing means and/or motive means include means adapted for attachment to the aorta and/or surrounding tissue within the thoracic cavity of the subject;

sensing means adapted for sensing the heart and generating sensing signals;

control means responsive to the sensing signals for generating the control signal(s); and

a power source for providing power to the motive means.

The device of the invention may operate in countersynchronisation to the heart (counterpulsation).

An advantage of the device and system of the present invention is that the risk of limb ischeamia associated with conventional IAB systems is avoided because there is no blood contact with the device whatsoever. Patient ambulation is also possible. Furthermore, there is no blood contact. Additionally the implantation technique used for the device of the invention is less invasive than those required for other devices. In particular, compared to the arrangement taught in US Patent No. 4,583,523, the device of the present invention provides a better outcome in term of reduced risk of infection, cosmesis and ease of implant and explant. A further advantage of the device and system of the present invention is that there is little risk to the patient in the event of device failure. Also there is no blood contact and no fluid containing balloon requirements.

The compressing means of the device of the present invention preferably includes a pair of individually actuated spaced apart pressure

plates or paddles shaped for receiving a portion of the aorta therebetween. Preferably, at least part of the inner face of each pressure plate or paddle is configured to fit the curve of at least a portion of the aorta between the pressure plates. In a particularly preferred form of the device of the present invention, the cross-section of each pressure plate is that of a circular or oval arc. Preferably, the pressure plates are shaped such that they do not pinch the aorta or completely close the aorta during the compression cycle. Preferably the longitudinal section of each pressure plate or paddle is substantially arc-shaped to fit the curve of the ascending aorta. The pressure plates or paddles may have flanges at their ends remote from the motive means so that they do not present a sharp edge. The pressure plates or paddles may have small holes therein to allow tissue in growth and preserve the plates in place.

In a preferred form of the invention, the device is adapted for compression of the ascending aorta. An upper mid-line sternotomy provides easy surgical access to the ascending aorta and has the further advantage of not being very painful for the patient. Minimum incision is required in this procedure. In this mode of use of the device of the invention, the compressing means is preferably adapted to squeeze approximately 10-15 ml of blood from the ascending aorta in each compression cycle.

The device of the invention may be used with the descending aorta, however, the compressing means needs to be of larger dimensions than in the case of compression of the ascending aorta because approximately 20-30 ml of blood has to be displaced from the descending aorta in each compression cycle. Implantation of the device for compression of the descending aorta may be achieved by a hemisternotomy.

The spaced apart pressure plates may be joined or hinged at one or both ends. In this latter case, the pressure plates are preferably formed from a deformable material (for example nitinol material).

Preferably, the motive means drives the pressure plates via a pair of arms, each arm being associated with a respective one of said pressure plates. Preferably, the arms are such that they allow soft tissue to squeeze out when the arms move through the tissue. The arms may be strut-like to reduce resistance to movement by surrounding tissue.

The motive means of the device of the invention may be any means that is capable of cyclically actuating and de-activating the pressure plates to

cyclically compress and decompress the aorta. The motive means may be a mechanical or an electromechanical device. The motive means may be an electric motor/cam arrangement. The motive means is preferably a solenoid drive or a rod solenoid. The motive means may include spring mounted arms driven by a pulse of power to hinged solenoids or the like to drive the pressure plates towards each other and thereby compress the aorta. An example of a suitable motive means is an adaptation of the solenoid actuator described in US Patent No. 4,457,673, the disclosure of which is incorporated herein by reference. The motive means may be based on that used in the Novacor N100 Left Ventricular Assist System.

The motive means is preferably enclosed in an air-tight rigid housing.

The motive means may be designed so that in the event of failure, it automatically goes into neutral with the arms spread apart so that the aorta is not compressed, thus minimising risk to the patient.

The motive means may include or be associated with means for detecting speed and completeness of actuation and de-activation of the pressure plates, for example, arm position sensors, or means for measuring arterial blood pressure or flow, and/or intrachamber pressure.

The means adapted for attachment to the aorta and/or surrounding tissue of the subject may be any suitable means. For example, the attachment means may be adapted for suturing and/or gluing the compressing means or motive means to the aorta or the surrounding tissue within the chest cavity. The attachment means may be suturing tabs. The attachment means may be apertures allowing ingrowth of tissue and/or surface portions adapted to promote tissue growth into or onto the compressing means and/or the motive means so as to hold the device in position relative to the aorta. For example, the pressure plates or paddles may have a plurality of holes through which the plates may be sutured to the aorta. Alternatively, the attachment means may be pressure plates shaped to "snap" on to, or encircle, the aorta which, together with the soft tissue surrounding the device, support the device in position relative to the aorta.

The sensor means may be means detecting a selected physiological event associated with heartbeat. The sensor means may be any means for producing an ECG. Means for detecting the action potentials of the cardiac muscles, for example electrodes, are well known to those skilled in the art and will not be described in detail here.

The control means may be any means capable of providing an output to actuate the motive means in response to signal(s) providing the sensor means.

The control means may provide signals to the motor means to countersynchronise compression of the aorta with the heart beat to provide counterpulsation, for example, aorta compression may commence with aortic valve closure (ventricular diastole), whilst aorta release occurs just prior to contraction/ejection (ventricular systole).

The power means may be an internal and/or external battery, or TET (transcutaneous electronic transfer).

De-activation of the compressing means may be timed to the R wave of the ECG and may be adapted for adjustment either manually or automatically. The dicrotic notch on the arterial pressure wave may provide the signal for actuation of the compressing means.

In yet a further aspect, the present invention provides a method for improving blood circulation in a subject, the method including implanting a device in accordance with the invention fully within the thoracic cavity of a subject, actuating the compressing means periodically in synchrony with the diastole period to compress the aorta; and alternating the period of actuation with periods of deactivation of the compressing means thereby allowing the aorta to return to its uncompressed shape.

The system and device of the invention allow relief/recovery from chronic heart failure whilst allowing the subject to move around freely without being constrained by a large external pumping device.

In order that the nature of the present invention might be more clearly understood, particular embodiments of the invention will now be described in relation to the accompanying drawings. It is to be understood that the following embodiments are not to be taken as limiting the invention as described in the foregoing description.

Referring to the Figures, Figures 1a and Figure 1b are schematic drawings showing an embodiment of a device **10** in accordance with the invention implanted in the thoracic cavity of a subject **99**. The device includes a housed hinged solenoid **2** driven by pulses of electrical power from controller/battery **14** to actuate wedge-shaped plates **4** via arms **3**. The wedge-shaped plates surround the ascending portion of the aorta **15** so that when the plates are actuated, that part of the aorta between the plates is

compressed. The plates have a plurality of holes **6** that provide means for suturing the plates to the aorta and permit ingrowth of tissue therethrough.

Figures 2a and 2b are detailed schematic drawing of solenoid **4** hinged at **8** with arcuate plates **26** in the de-activated (resting) position (Figure 2a) and in the actuated position (Figure 2b) compressing aorta **15**. In this arrangement, the plates **26** are soft form moulded and are actuated by the hinged solenoid via arms **23**.

Figures 3 to 6 are schematic drawings of alternative embodiments of devices in accordance with the present invention.

Figure 3 shows an arrangement in which the compression plates **34** are actuated via arms **33** with each arm being acted on by a respective rod solenoid **38** acting through springs **37** between the solenoid rod and the respective arm.

Figure 4 shows an arrangement wherein solenoids **48** act on deformable nitinol plates **44** connected together at either end **47** to encircle the aorta **15**.

Figures 5a and 5b show a further embodiment of the device of the invention in which wedge-shaped plates **54** are connected together at one end 57 and each plate is actuated by solenoids **58** acting through arms **53**. As can be seen from Figure 5b, the wedge-shaped plates effectively conform to the shape of the ascending aorta **15**.

Figure 6 is a block diagram of a cardiac assist system constructed in accordance with the invention.

Initiation of the compression of the aorta by the compression plates is accomplished by energisation of the solenoids. This energisation is under the control of a control means **100** which activates the solenoids of the motive means **1** in response to signals received from an ECG monitor **102** or systemic arterial blood pressure **103** or the like. The ECG monitor and/or the control means may be implanted or be on the body of the subject.

In operation, de-activation of the compressing means effectively unloads the left ventricle allowing the aorta to return to its usual circular shape. The expansion of the aorta between the de-activated plates causes a pressure drop in the aorta, facilitating left ventricle ejection (ie unloads the heart). The plates are then activated to compress the aorta, after the heart has finished ejecting blood into the aorta, to thereby squeeze blood out of the volume of the aorta compressed by the compressing means and augment the

diastolic pressure. Coronary artery blood flow to the left ventricle occurs predominantly in diastole so compression of the aorta also augments coronary blood flow.

It will be appreciated that the system and device of the present invention, in its preferred form, is designed to be very simple with no valves, balloons, seals or rotors, no blood contact and a much lower morbidity risk compared to LVADs. The device and system allows the heart to remain totally un-instrumented, and the device, by effective counterpulsation in the aorta, augments the cardiac output up to 15-20%. All natural blood pathways are maintained. Pulsatile blood flow is also maintained. The patient is able to ambulate and there is no risk of leg ischaemia.

The present invention provides for long term relief and/or stabilization/ of or recovery from chronic heart failure. Moreover the present invention may be a suitable bridging device for transplantation.

The device and system of the above-described embodiments improve cardiac work efficiency by reducing the afterload (pressure/resistance to flow which the heart has to overcome to eject blood) during systole (ejection phase), by augmenting diastolic aortic blood pressure to maintain a greater mean arterial pressure, and by increasing left ventricular coronary artery blood flow during diastole.

References:

[1] The SOLVD Investigators. Effects of enalapril on survival in patients with reduced left ventricular ejection fractions and congestive heart failure. New Engl J Med 1991:325:293-302.

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[3] Sarris GE, Moore KA, Schroeder JS, et al. Cardiac transplantation in the cyclosporin era. J Thorac Cardiovasc Surg 1994;108:240-52.

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It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. For example, although the invention has been described in specific reference to compression of the aorta, the devices, systems and methods of the present invention can equally be used for the compression of the pulmonary artery to effectively act as a right ventrical assist device, and the present invention extends to this alternative aspect. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

Dated this tenth day of June, 1999.

WILLIAM S PETERS
Patent Attorneys for the Applicant:

F B RICE & CO

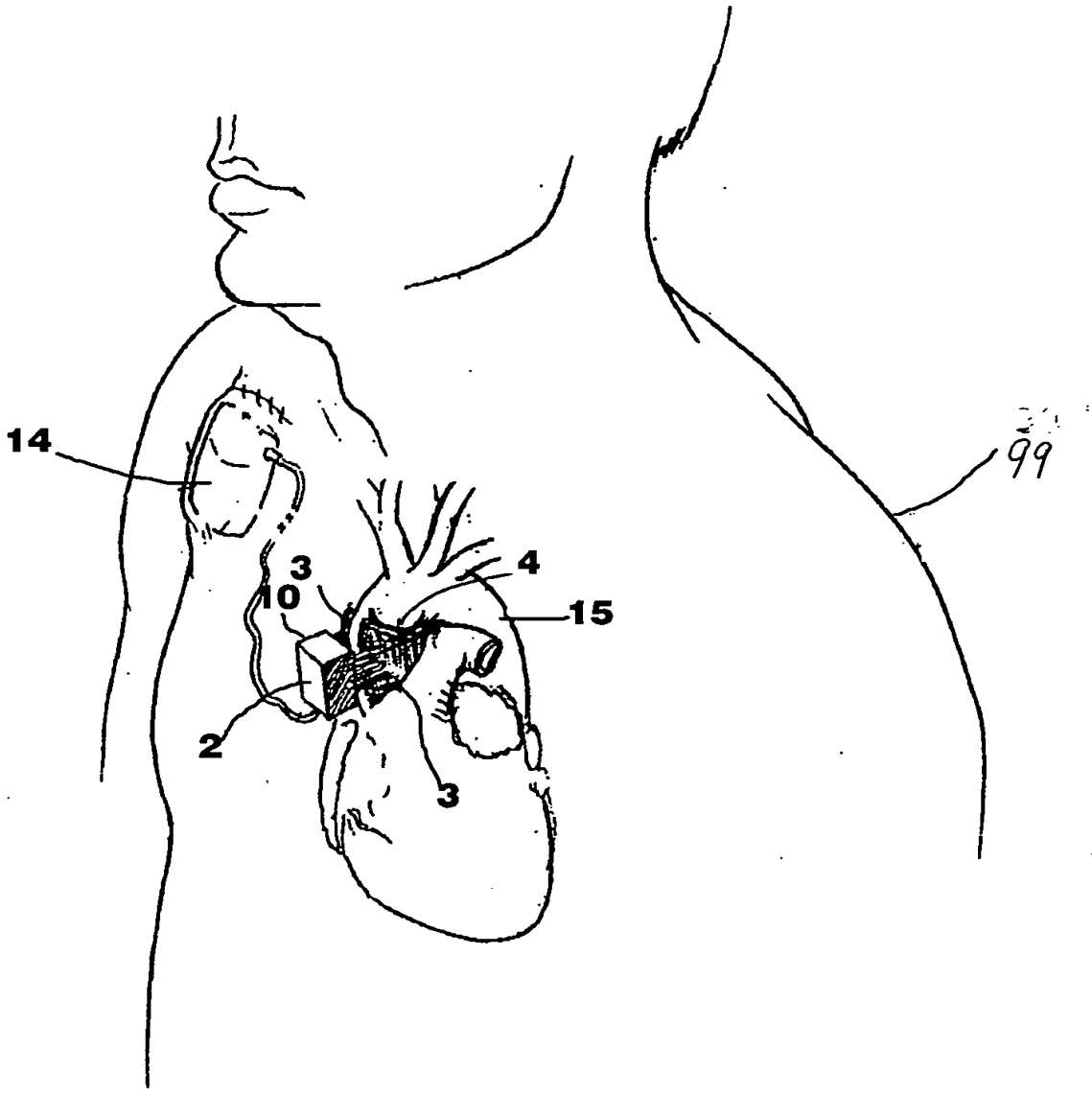


Fig. 1a

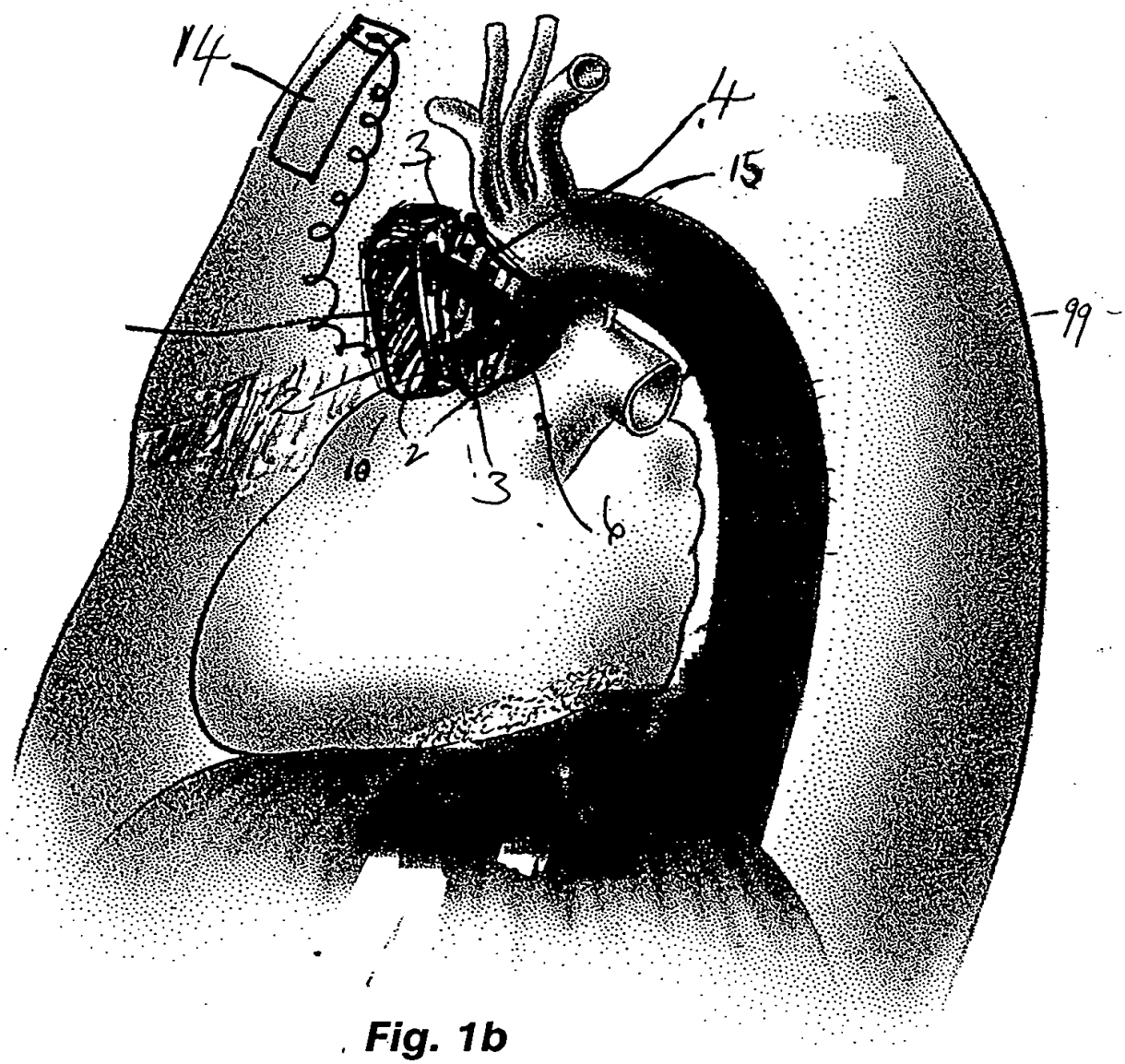
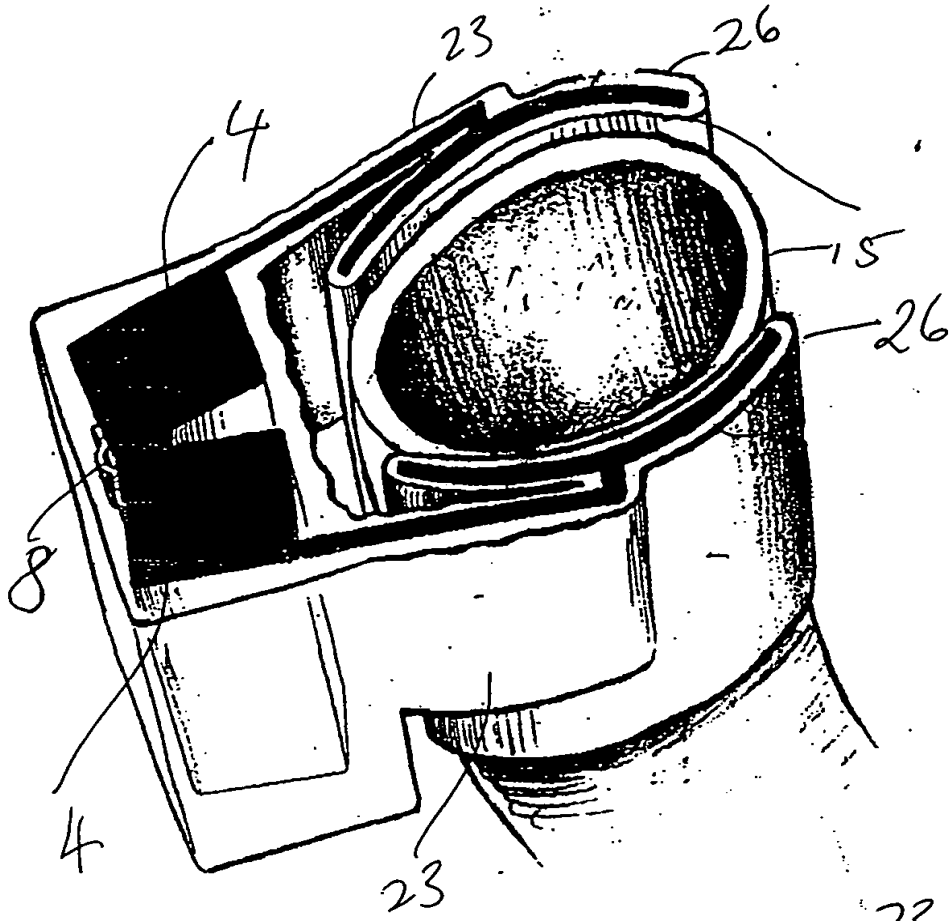
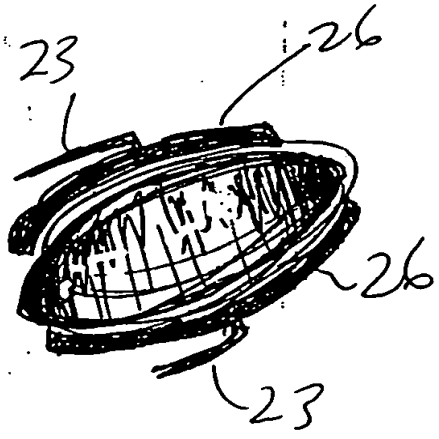


Fig. 1b



2a



2b

Fig. 2

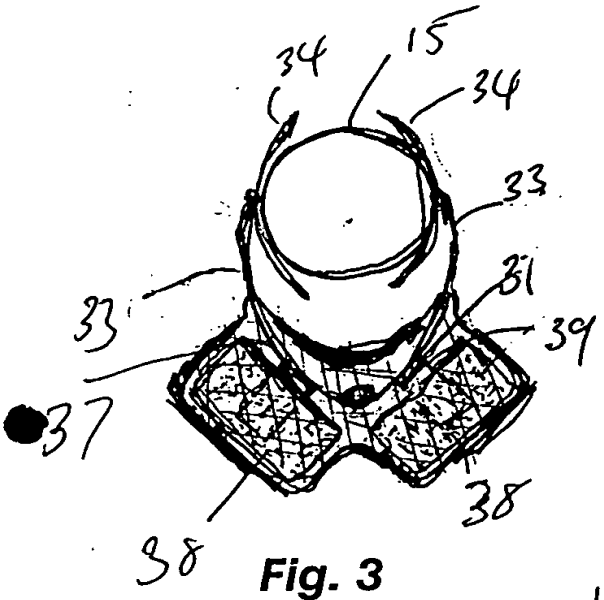


Fig. 3

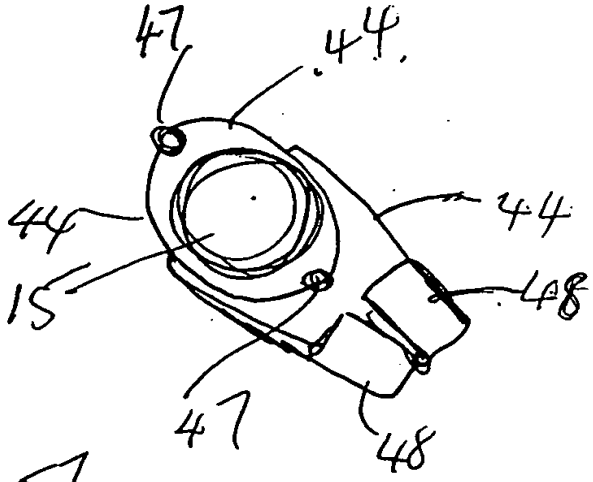


Fig. 4

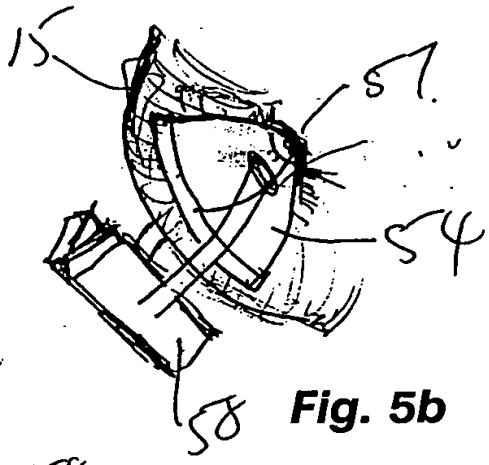


Fig. 5b

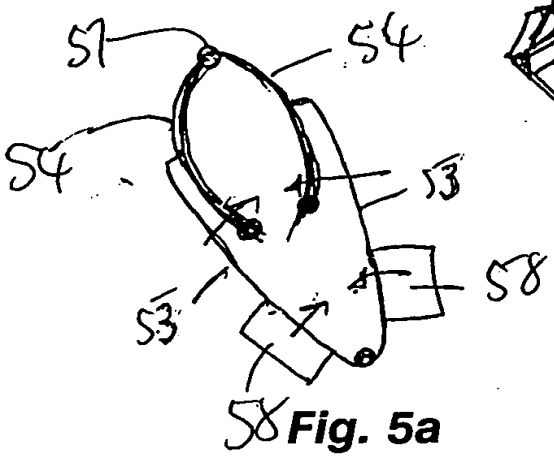


Fig. 5a

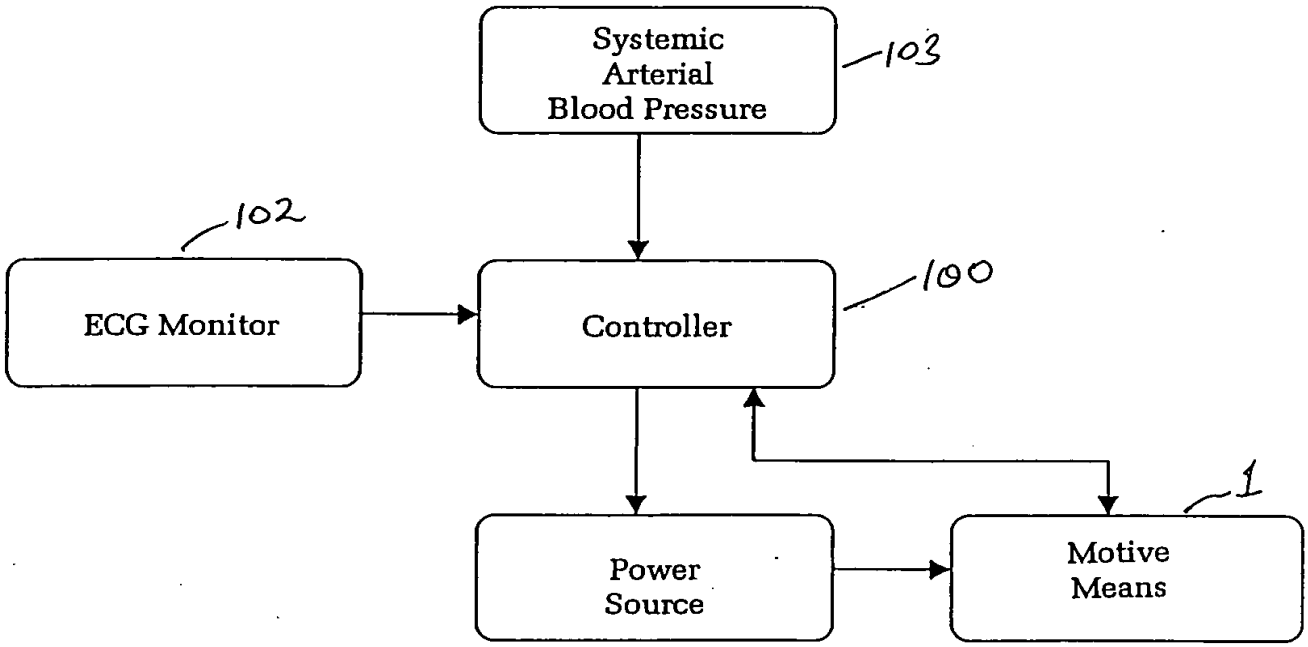

Systemic
Arterial
Blood Pressure
103
102
ECG Monitor
Controller
100
Power
Source
Motive
Means
1

Fig. 6